

## REMARKS

### Status of the Claims

#### *Pending claims*

Claims 1 to 16, 19 to 22 and 24 to 42 are currently pending.

#### *Claims amended and added in the instant amendment*

In the present response, claims 1, 2, 4 to 6, 9, 11, 27 and 41 are amended and claims 43 to 56 are added. Accordingly, after the entry of the instant amendment, claims 1 to 16, 19 to 22 and 24 to 56 will be pending and under examination.

#### *Outstanding Rejections*

Claims 1 to 16, 19 to 22 and 24 to 42 are rejected under 35 U.S.C. 112, second paragraph. Claims 1 to 7, 10 to 16, 19, 27 to 29, 31 to 34 and 39 to 42 are newly rejected under 35 U.S.C. 102(e) as allegedly anticipated by Lauto et al. 2001 (U.S. Patent 6,323,037 B1), filed April 6, 1999 (hereinafter "Lauto"). Applicants respectfully traverse all outstanding objections to the specification and rejections of the claims.

### Issues under 35 U.S.C. §112, second paragraph

The Patent Office has rejected claims 1 to 16, 19 to 22 and 24 to 42 for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard and the invention.

#### *The term "having a predetermined shape"*

The Patent Office alleges the term "having a predetermined shape" in claim 1 is indefinite. The instant amendment addresses this issue.

#### *The term "at least partially denatured"*

The Patent Office alleges the term "at least partially denatured" in claim 1 and claims 11 and 12 is indefinite.

Applicants respectfully note that when claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, they satisfy the requirement of section 112, second paragraph. The amount of detail required to be included in claims depends on the

particular invention and the prior art, and is not to be viewed in the abstract but in conjunction with whether the specification is in compliance with the first paragraph of section 112.

The instant amendment addresses this issue. After entry of the instant amendment, the biomolecular solder of claim 1 and the method of claim 11 comprises denaturing a proteinaceous substance such that at least a portion of the proteinaceous substance bonds together.

The specification clearly provides guidance on the limitations and scope of this phrase. For example, on page 15, lines 29 to 30, the specification notes that different parts of the solder may be denatured to different extents. The specification on page 16, lines 12 to 30, describes using a laser to selectively denature a solder of the invention. The specification on page 22, lines 10 to 18, describes methods of denaturing proteinaceous substances to make the solder of the invention. Thus, from the teachings provided in the specification it would have been clear to the skilled artisan that complete denaturation of the proteinaceous solder is not necessary to achieve the claimed invention. Furthermore, the claims, read in light of the specification, reasonably apprised those skilled in the art both of the utilization and scope of the invention.

Accordingly, Applicants respectfully aver that in the context of the invention as a whole the specification reasonably apprised those skilled in the art both of the utilization and scope of the invention with respect to partial denaturation of the solder of the invention.

*The term "having a predetermined shape"*

The Patent Office alleges the term "or an analogue thereof" in claim 1 is indefinite. The instant amendment addresses this issue.

Issues under 35 U.S.C. §112, second paragraph

Claims 1 to 7, 10 to 16, 19, 27 to 29, 31 to 34 and 39 to 42 are newly rejected under 35 U.S.C. 102(e) as allegedly anticipated by Lauto.

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention.

Applicants respectfully aver that Lauto does not teach methods of making a biomolecular solder comprising partial or complete denaturation. Lauto is silent on the issue of denaturation. For example, Lauto states (on the paragraph spanning columns 2 and 3):

In order to achieve high concentrations of active compound in the composition, any suitable physical, chemical or mechanical process can be utilized, particularly, mechanical compression, thermal treatment, irradiation, various chemical treatments, combinations thereof, and the like. Whatever means of combining the active compound and solvent are chosen, the resulting combination is, preferably, homogeneous.

Lauto also states (the paragraph of column 4, lines 38 to 49):

Additionally, the composition can undergo reversible or partially reversible physical or chemical treatments in order to improve the malleability of the composition, alter the composition's ability to form various shapes, or alter the composition's mechanical properties. For example, a composition with a high concentration of albumin can be hydrated to increase its flexibility and malleability. Subsequently, the composition can be molded into the most suitable shape and dehydrated so that the composition can assume its original state. The solid albumin solder also can be exposed to warm water vapor to increase the solder elasticity.

Thus, the use of thermal energy sources as described in Lauto is not for denaturation purposes, but to improve malleability by providing mild and humid warmth, e.g., by way of warm water vapor, or, to achieve high concentrations of active compound in the composition. Providing mild and humid warmth by way of warm water vapor, provides partial rehydration to allow greater flexibility of already prepared solid solder composition.

The solid solder composition described in Lauto is based on the choice of high concentration of protein and appropriate solvent to achieve insolubility as a way of obtaining the appropriate consistency and physical properties for the solder. Any additional treatments of the protein solder suggested in Lauto is subsequent to preparation of the final solder composition and serve merely to improve its handling, not to impart insolubility by way of denaturation of the protein or any part of it.

In contrast, the Applicants' invention is directed to methods comprising denaturing at least a portion of a proteinaceous substance, or, solder compositions made by a process comprising denaturing at least a portion of a proteinaceous substance. In one aspect, the proteinaceous substance is denatured such that, when shaped, the shape of the solder is

essentially maintained and the solubility of the proteinaceous substance is reduced in a physiological fluid at body temperature. In one aspect, the denaturing results in an intramolecular bonding to create a solid or semi-solid state of the protein solder. In one aspect, this can have advantageous properties and superior bonding quality, for example, the initial protein concentration can be lower because the final properties of the solder do not depend on protein concentration but on a complete or partial denaturation of the protein.

Further, and specifically in relation to input of thermal energy, the denaturation of the protein in one aspect of the Applicants' invention is achieved by levels of heat which are well above the "warm water vapour" temperature suggested by Lauto. In one aspect, the amount of heat applied in the Applicant's invention is intended to completely or partially denature the proteinaceous solder to, e.g., cause the solder to bond within itself and have the solder become less soluble in water; see, for example, page 22, lines 10 to 18 and page 23, line 1, of the specification. The approach taken by the Applicant also enables one to use a lower concentration of protein, in contrast to Lauto. Thus, the biomolecular solder of the claimed invention can have different properties when compared to the compositions taught by Lauto.

Accordingly, because Lauto does not teach or suggest methods of making a solder by partially, or to any extent, denaturing a proteinaceous substance to generate a solder, it is not a single prior source containing each and every limitation of the claimed invention. Applicants respectfully submit that the rejection of claims 1-17, 10-16, 19, 27-29, 31-34 and 39-42 under 35 U.S.C. §102(e) may be properly withdrawn.

#### CONCLUSION

In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §112, second paragraphs and 35 U.S.C. §102(e). Applicants believe all claims pending in this application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

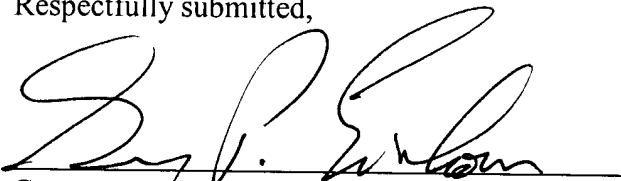
If necessary, please apply additional and necessary charges, and apply all credits, to Deposit Account No. 06-1050.

If the Examiner believes a telephone conference would expedite prosecution of this application, Applicants respectfully request a telephonic interview with the undersigned at (858) 678-5070.

Respectfully submitted,

Date:

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